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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AVENTIS PHARMACEUTICALS INC., Plaintiff, vs. SANDOZ INC., Defendant.	Civil Action No. 04-222 (JAG) **COMPLAINT**

Plaintiff, Aventis Pharmaceuticals Inc. ("Aventis"), by its attorneys, for its complaint against Defendant, Sandoz Inc. ("Sandoz"), alleges as follows:

THE PARTIES

1. Aventis is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business in this judicial district at 300 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807. Aventis is engaged in the business

of researching, developing, manufacturing, and selling prescription pharmaceutical products.

2. On information and belief, Sandoz is a corporation organized and existing under the laws of the state of Colorado, having a principal place of business in this judicial district at 2400 Route 130 North, Dayton, New Jersey 08810 and at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540. Sandoz is in the business of marketing pharmaceutical products, including generic pharmaceutical products.

THE NATURE OF THE ACTION

3. This is an action for patent infringement, arising under the United States Patent Laws, 35 U.S.C. § 100, *et seq*.

JURISDICTION AND VENUE

4. The jurisdiction of this Court is properly founded under 28 U.S.C. §§ 1331 and 1338(a), as well as 28 U.S.C. §§ 2201 and 2202.

5. Venue in this Court is proper under 28 U.S.C. §§ 1391 and 28 U.S.C. § 1400(b). Sandoz maintains a substantial presence in this judicial district and has continuous and systematic contacts with New Jersey. On information and belief, the corporate headquarters of Sandoz's generic drug business is located at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540. Additionally, on information and belief, Sandoz maintains a large research and development operation directed to its generic drug operations at 2400 Route 130 North, Dayton, New Jersey 08810. Accordingly, Sandoz is subject to personal jurisdiction in this judicial district.

THE AVENTIS PATENTS IN SUIT

6. United States Patent No. 6,113,942 ("the '942 patent") was duly and legally issued on September 5, 2000, and is entitled "Pharmaceutical Compositions for Piperidinoalkanol Compounds." The '942 patent is assigned of record to Aventis.

7. United States Patent No. 5,932,247 ("the '247 patent") was duly and legally issued on August 3, 1999, and is entitled "Pharmaceutical Compositions for Piperidinoalkanol Compounds." The '247 patent is assigned to Hoechst Marion Roussel, Inc., a predecessor in interest to Aventis.

8. United States Patent No. 5,855,912 ("the '912 patent") was duly and legally issued on January 5, 1999, and is entitled "Pharmaceutical Compositions for Piperidinoalkanol Compounds." The '912 patent is assigned to Hoechst Marion Roussel, Inc., a predecessor in interest to Aventis.

9. United States Patent No. 5,738,872 ("the '872 patent") was duly and legally issued on April 14, 1998, and is entitled "Pharmaceutical Compositions for Piperidinoalkanol Compounds." The '872 patent is assigned to Hoechst Marion Roussel, Inc., a predecessor in interest to Aventis.

ACTS GIVING RISE TO THIS ACTION

10. Aventis is the holder of a New Drug Approval ("NDA") from the U.S. Food and Drug Administration ("FDA") for fexofenadine hydrochloride 30 mg, 60 mg and 180 mg tablets. Pursuant to this and other approvals, Aventis markets pharmaceutical products containing fexofenadine hydrochloride under the trademark Allegra®. The Aventis patents in suit described above include claims directed to Aventis's Allegra® products.

11. On information and belief, Sandoz has filed with the FDA an Abbreviated New Drug Application ("ANDA") seeking approval to market fexofenadine hydrochloride

30 mg, 60 mg and 180 mg tablets. In a letter dated December 9, 2003 (the "Notification Letter"), Sandoz notified Aventis that it had filed ANDA 76-707 pursuant to Section 505(j)(1) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)(1)), on the basis of bioequivalence and/or bioavailability studies in comparison to Aventis's NDA.

12. In the Notification Letter, Sandoz asserted that, pursuant to its ANDA filing, it seeks to engage in commercial manufacture, use and sale of fexofenadine hydrochloride 30 mg, 60 mg and 180 mg tablets prior to the expiration of the '912, '942 and '247 patents, each of which is listed in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluation*, ("Orange Book") as being applicable to Aventis's Allegra® tablets. The '872 patent was not listed in the Orange Book and, thus, was not addressed in Sandoz's ANDA. On information and belief, Sandoz intends to engage in commercial manufacture and sale of fexofenadine tablets upon receiving FDA approval to do so.

13. Additionally, in its Notification Letter, Sandoz asserted that its ANDA included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a so-called "paragraph iv certification," asserting that, in Sandoz's opinion, the '912, '942 and '247 patents are invalid or not infringed by Sandoz's fexofenadine tablets. Sandoz asserted that its fexofenadine products do not contain certain specific inert ingredients or "excipients" and that, therefore, the Sandoz fexofenadine products do not infringe the Aventis patents. However, Sandoz did not state what specific inert ingredients are employed in the Sandoz fexofenadine products. On information and belief, however, the inert ingredients used in the Sandoz fexofenadine products are at least equivalent to those referenced in the Aventis patents. On information and belief, Sandoz's ANDA is predicated on its generic products being bioequivalent to Aventis's Allegra® NDA products.

COUNT I - INFRINGEMENT OF THE '912 PATENT

14. Aventis realleges and incorporates by reference paragraphs 1-13.

15. Sandoz's filing of an ANDA seeking to engage in commercial manufacture, use and sale of fexofenadine hydrochloride 30 mg, 60 mg and 180 mg tablets prior to the expiration of the '912 patent, is an act of infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2).

16. Sandoz's actions constitute knowing and willful infringement of the '912 patent.

COUNT II - INFRINGEMENT OF THE '942 PATENT

17. Aventis realleges and incorporates by reference paragraphs 1-16.

18. Sandoz's filing of an ANDA seeking to engage in commercial manufacture, use and sale of fexofenadine hydrochloride 30 mg, 60 mg and 180 mg tablets prior to the expiration of the '942 patent, is an act of infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2).

19. Sandoz's actions constitute knowing and willful infringement of the '942 patent.

COUNT III - INFRINGEMENT OF THE '247 PATENT

20. Aventis realleges and incorporates by reference paragraphs 1-19.

21. Sandoz's filing of an ANDA seeking to engage in commercial manufacture, use and sale of fexofenadine hydrochloride 30 mg, 60 mg and 180 mg tablets prior to the expiration of the '247 patent, is an act of infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2).

22. Sandoz's actions constitute knowing and willful infringement of the '247 patent.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '872 PATENT

23. Aventis realleges and incorporates by reference paragraphs 1-22.

24. On information and belief, Sandoz is expecting approval of its NDA seeking to authorization to market its generic 30 mg, 60 mg and 180 mg fexofenadine tablets.

25. On information and belief, Sandoz plans to begin marketing, selling, and offering to sell its fexofenadine tablets soon after the FDA approves its ANDA.

26. Such conduct will constitute direct infringement of one or more claims of the '872 patent under 35 U.S.C. § 271(a).

27. Sandoz's filing of an ANDA and Sandoz's intention to begin manufacturing, selling or offering for sale generic fexofenadine 30 mg, 60 mg and 180 mg tablets upon receiving FDA approval create an actual case or controversy with respect to infringement of the '872 patent.

28. Upon FDA approval of Sandoz's ANDA, Sandoz will infringe the '912, '942, '247 and '872 patents by making, using, selling or offering to sell generic fexofenadine 30 mg, 60 mg and 180 mg tablets in the United States, unless enjoined by the Court.

29. On information and belief, Sandoz had (and continues to have) notice of the aforementioned patents at the time of its infringement. Therefore, Sandoz's infringement has been and continues to be deliberate and willful.

30. Aventis has no adequate remedy at law for Sandoz's infringement and, accordingly, will be substantially and irreparably damaged and harmed if Sandoz's infringement is not preliminarily and permanently enjoined.

WHEREFORE, Aventis respectfully requests the following relief:

a) A judgment declaring that Sandoz has infringed and that Sandoz's making, using, selling and offering for sale of generic fexofenadine tablets will infringe each of the '912, '942, '247 and '872 patents and that such infringement is willful;

b) A judgment providing that the effective date for any FDA approval issued to Sandoz pertaining to its generic fexofenadine tablets shall be no earlier than the expiration date of the last to expire of the '912, '942, '247 and '872 patents;

c) A preliminary and permanent injunction enjoining Sandoz from making, using, selling, and/or offering to sell generic fexofenadine tablets or otherwise infringing the '912, '942, '247 and/or '872 patents;

d) Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

e) Costs and expenses in this action; and

f) Such further and additional relief as the Court may deem just and proper.

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Dated: January 20, 2004

RULE 11.2 CERTIFICATION

I hereby certify that the matter in controversy is not the subject of any other action pending in any court, or any pending arbitration or administrative proceeding. The patents in suit and infringement thereof by other generic drug manufacturers are the subject of the following civil actions pending in this District: *Aventis Pharmactuticals, Inc. et al. v. Barr Laboratories*, Civil Action No. 01-3627 (JAG); *Aventis Pharmactuticals, Inc. et al. v. Impax Laboratories, Inc.*, Civil Action No. 02-1322 (JAG); *Aventis Pharmactuticals, Inc. et al. v. Teva Pharmaceuticals*, Civil Action No. 03-487 (JAG); *Aventis Pharmactuticals, Inc. et al. v. Mylan Pharmaceuticals*, Civil Action No. 03-1179 and *Aventis Pharmactuticals, Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, Civil Action No. 03-1180 (JAG)

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Dated: January 20, 2004